The Biomedical Translational Research Information System

Introduction to BTRIS

July 2014





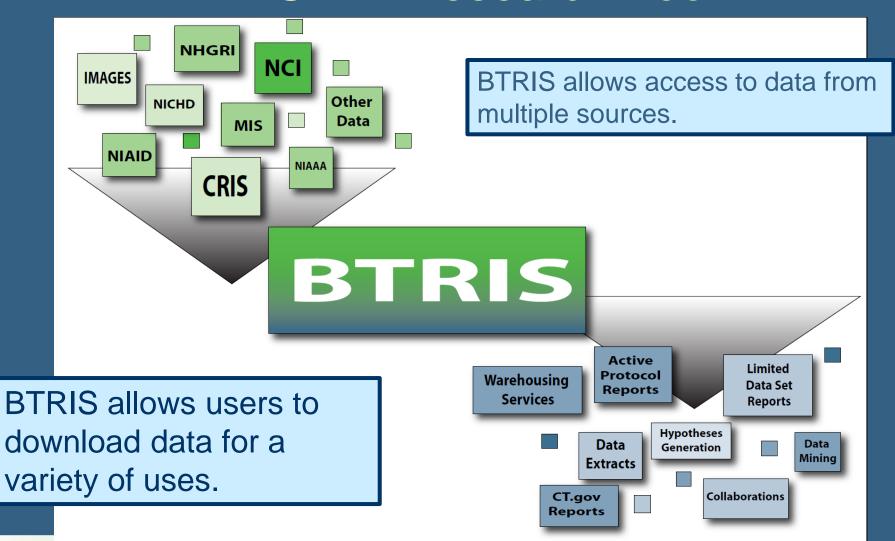
Introduction to BTRIS

- Welcome to this introduction to BTRIS (pronounced BEE-triss)
- BTRIS is a an application that provides access to clinical research data collected at the NIH
- It has a data repository and a user interface that allows NIH researchers to access data from their own active protocols and data (in deidentified form) across all protocols





BTRIS - A Research Tool







Using Data From BTRIS

- Data sets can be downloaded into other programs for further analysis
 - Microsoft Excel
 - Microsoft Access
 - Statistical analysis programs like SAS and SPSS
- Data are available in identified format (with personal identifiers) and limited data set (no personal identifiers) formats





Who Uses BTRIS?

- There are different types of users:
 - Researchers managing data for active protocols
 - Researchers posing questions for hypothesis development
 - Data managers monitoring protocols for quality assurance purposes
 - Data extractors who download data for use by institute researchers





BTRIS Home Page



BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM

■ National Institutes of Health ■

Home

NIH BTRIS

>> BTRIS Presentations

- >> Publications Using BTRIS
- >> Publications About BTRIS
- >> <u>Laboratory for</u> Informatics Development

>> Staff Only

The Biomedical Translational Research Information System (BTRIS) is a resource available to the NIH intramural community that brings together clinical research data from the Clinical Center and other NIH Institutes and Centers. BTRIS provides clinical investigators with access to identifiable data for the subjects on their own active protocols, while providing all NIH investigators with access to data without personal identifiers across all protocols. Data are available from 1976 to the present.

BTRIS Functions

Active Protocols

- Reports by protocol
- Labs, medications, documentation, images
- · Download files for analysis

Hypothesis Generation

- Query date without personal identifiers
- 1976 to the present

Subject Attribution

- Check protocol attribution
- Add subjects based on signed consents
 Set preferences for notifications

Clinical Trials Reporting

FDAAA compliance made easy

Active Protocol Data is available in identified format to NIH intramural research team members associated with a protocol. View Introduction to BTRISfor additional details.

Hypothesis Generation allows NIH intramural researchers to access clinical research data without personal identifiers from the NIH Clinical Center systems from 1976 to the present. For an overview of BTRIS Data Without Personal Identifiers see https://www.youtube.com/watch?v=5yHiVSMew7k

Subject Attribution is managed through a custom application called Preferences. Users can confirm the association of a subject with an active protocol, or set thresholds for notifications and permissions related to secondary data use.

ClinicalTrials.gov allows NIH intramural researchers to assemble and format data required for FDAAA reporting compliance (use this link http://clinicaltrials.gov/ct2/manage-recs/fdaaa). Once the filing materials are complete in BTRIS, the user may automatically upload the file to ClinicalTrials.gov

About BTRIS

- >> BTRIS Town Hall 2013
- >>Introduction to BTRIS
- >> BTRIS Videos

BIRIS

This page is found at http://btris.nih.gov



BTRIS Internet Page



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Select the "Staff Only" link.





Query date without personal identifiers



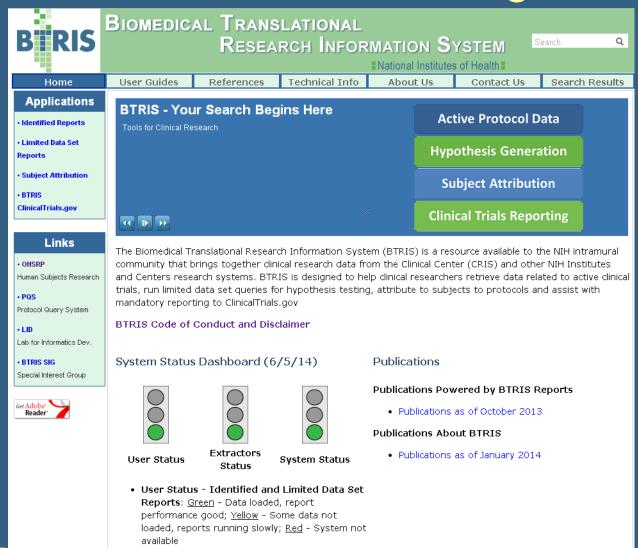
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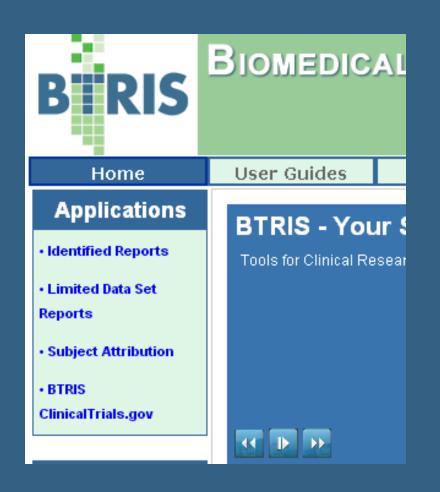
BTRIS Intranet Page







Access to BTRIS Applications

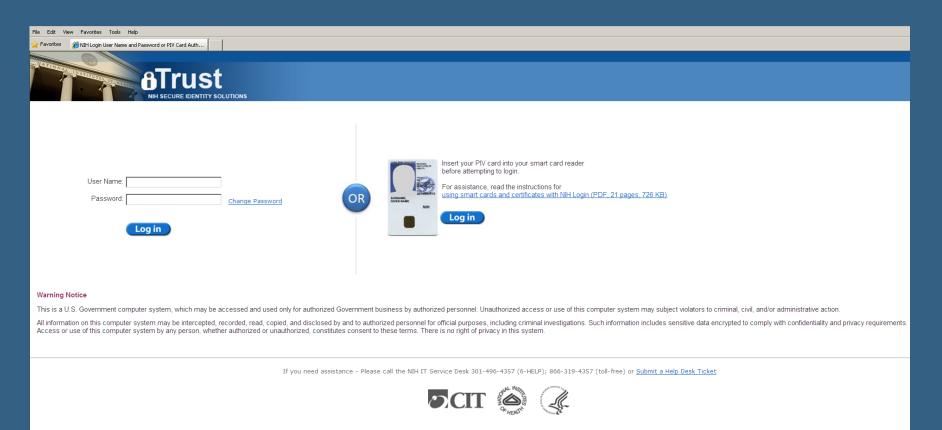


- From this point you can select a BTRIS application.
- We will begin with subject attribution and ClinicalTrials.gov.





Application Links Lead to BTRIS Log-in



Log-in to BTRIS using your NIH user name and password or your PIV card and PIN.





Preferences

BTRIS Preferences allow users to complete the following functions on their own:

- Attribute subjects to a protocol
- File a ClinicalTrials.gov report
- NOTE the BTRIS team assists users with adding users based on their research role

We will attribute a subject to a protocol





Subject Attribution



BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM

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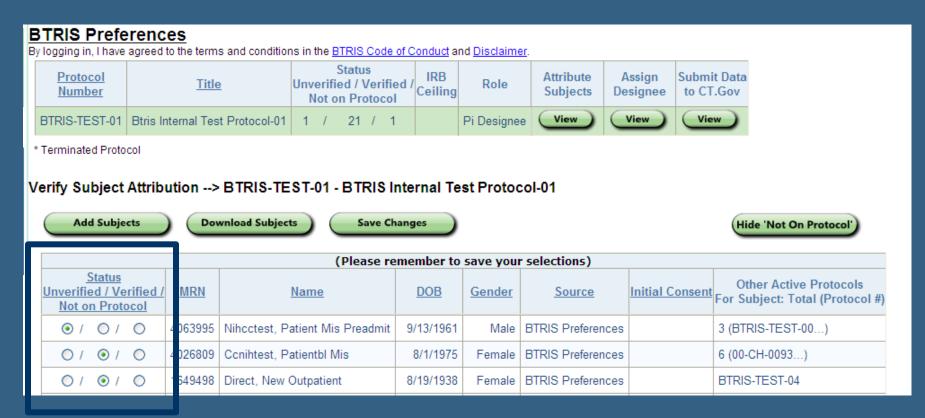
Home > Subject Attribution & Designee Assignment BTRIS Preferences **NIH BTRIS** By logging in, I have agreed to the terms and conditions in the BTRIS Code of Conduct and Disclaimer. BTRIS Preferences Status BTRIS Data Access Protocol IRB Attribute Assian Submit Data Title Unverified / Verified / Role Ceiling Subjects to CT.Gov Number Designee Not on Protocol Pi Designee View View View Btris Internal Test Protocol-01 21 / 1 * Terminated Protocol Resources Training & User Guides Presentations

- The main page of Preferences displays the protocols you may access.
- To attribute subjects select the view button under the "attribute subjects" column.





Verification

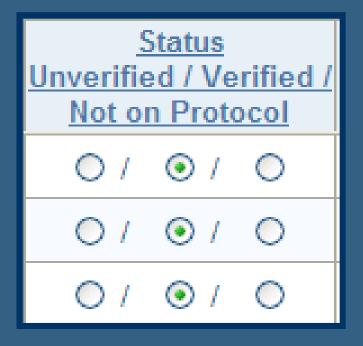


 A subject on a protocol has a status of "verified", "unverified" or "not on protocol"





Verification Status



- Selecting the middle radio button changes the subject status to verified.
- Only subjects with signed consents should be verified.
- Subjects must have a verified status to be included in reports.



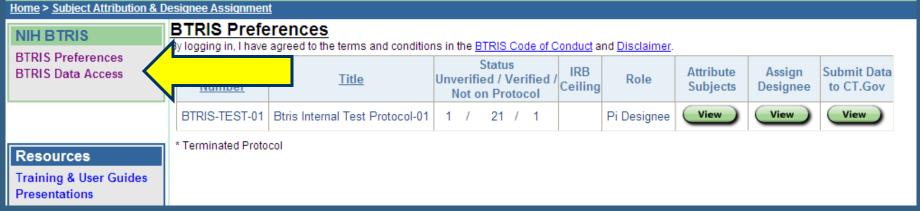


Access BTRIS Applications



BIOMEDICAL TRANSLATIONAL RESEARCH INFORMATION SYSTEM

■ National Institutes of Health ■

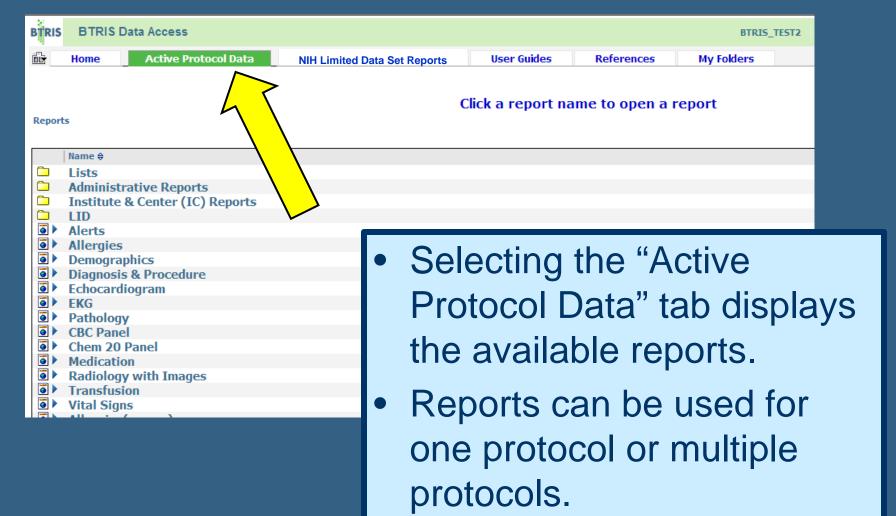


We will now move to BTRIS Data Access to run identified data reports for active protocols.





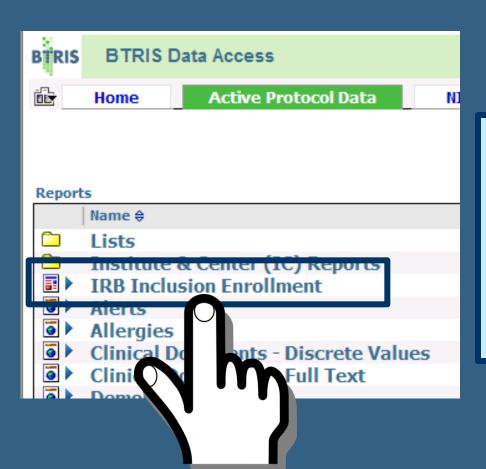
Use Data Access for Reports







Run a Report



Select the IRB
 Inclusion Enrollment
 report by clicking on
 the name of the
 report.





Report Prompt Page

		IRB I	inclusion	Enrollment R	eport				
Please select one Protocol Number first (this selection is mandatory) and all other prompts are optional. When you finish all your selection, please click "Run Report" button below to start running the report.									
			Cancel	Run Report					
The number Reports with You can verice Preferences	34 No subjects identified	subjects.	(Optional) Please Enter Range	e for Subject Initial Consent Date				
09-CC-99 09-CC-99 09-CC-N1	80 No subjects identified 90 No subjects identified 99 No subjects identified 37 No subjects identified		From:		■				
	59 (27 of 40 verified)		To:		■ -				
09-CH-01	85 All 6 verified 80 (11 of 12 verified) 85 All 35 verified	T							

The date filter in the IRB report is derived using the 'Initial Consent Date' of the subject, and if the 'Initial Consent Date' is not available, the start date of the protocol is used. The 'Initial Consent Date' can be viewed for subjects in the protocol in the Demographics Report

- Select the protocol from the list.
- Adding beginning and end dates is optional.
- Select the "Run Report" button.

IRB Inclusion Report

- Report includes all verified subjects in the protocol
- Report is created in a PDF format

Cumulative Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants

Is the NIH site responsible for conducting and coordinating the overall clinical study across multiple study sites (i.e. coordinating site)?

- Yes provide the numeric distribution (not percentages) for the total number of participants planned for the study. Provide separate tables for the following: 1) NIH CC Site, 2) All Other Domestic Sites Combined, and 3) Foreign Sites Combined. For additional guidance, see: http://inih-extramura-intranet.od.nih.gov/inih/topics/
- No complete the table only for the NIH CC site.

Select Site: NIH CC Site

Principal Investigator:

Study Title: BTRIS Internal Test Protocol-03

Total Enrollment:	27	Protocol Number: BTRIS-TEST-03				
NIH/CC	Other Domestic Sites	Foreign Sites	Total			
			Accrual Ceiling New Subject Since Last CR			
27			27 Aggregate Total Accrued			

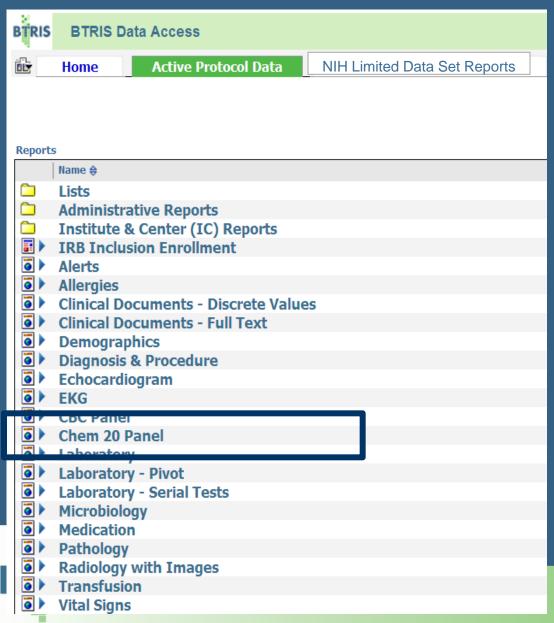
	Ethnic Categories									
Racial Categories	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	1	0	1	0	0	0	1	0	3
Asian	0	0	0	1	0	0	0	0	0	1
Native Hawalian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	3	5	0	0	1	0	0	1	0	10
White	0	5	0	1	0	0	1	0	0	7
More Than One Race	0	1	0	0	0	0	0	0	0	1
Unknown or Not Reported	0	0	0	0	1	0	2	2	0	5
Total	3	12	0	3	2	0	3	4	0	27

Generated by BTRIS on: Jul 21, 2014





Run a Chem 20 Report



- From the "Active Protocol" tab select the Chem 20 Panel Report.
- To select click on the name of the report.



Report Prompt Page

Chem 20 Report

Select "Protocol Number (s)" first (mandatory). All other prompts are optional. After completing desired prompts, click "Run Report" to begin running report.

Select all Deselect all

Run Report Cancel Please select one or more Protocol Number(s) The number in () (Optional) Please Click 'Subject List' to Display and Select One or More Subject(s)/MRN(s) indicates the verified subjects in the protocol. Reports will include data on ONLY verified subjects. You can verify, exclude or add subjects in BTRIS Subject List Preferences Select the 09-C-1234 -- All 13 verified protocol or 09-C-9990 -- The sole subject in the study is ver 09-CC-0135 -- All 36 verified 09-CC-0186 -- (58 of 59 verified) protocols to 09-CC-0217 -- (28 of 35 verified) 09-CC-N202 -- All 1561 verified 09-C-1234 -- All 13 verified 09-CH-0059 -- (27 of 40 verified) include in the 09-CH-0063 -- All 19 verified 09-C-9990 -- The sole subject in the study is ver 09-CH-0085 -- All 6 verified 09-CH-0180 -- (11 of 12 verified) 09-CC-0135 -- All 36 verified report. 09-CH-0185 -- All 35 verified 09-CC-0186 -- (58 of 59 verified) Select all Deselect 09-CC-0217 -- (28 of 35 verified) Date ranges can 09-CC-N202 -- All 1561 verified be used. 09-CH-0059 -- (27 of 40 verified) 09-CH-0063 -- All 19 verified (Optional) Please enter Collected Date range 09-CH-0085 -- All 6 verified From: 09-CH-0180 -- (11 of 12 verified) To: ₩-09-CH-0185 -- All 35 verified



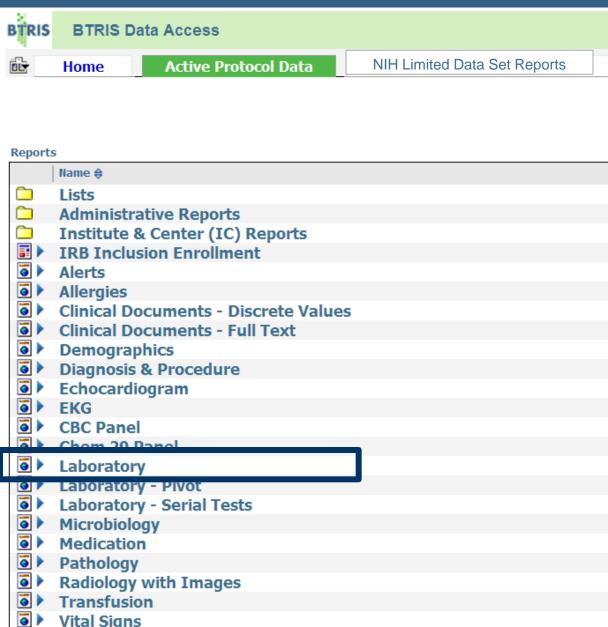


Chem 20 Report

	Subject Count: 13 Record Count: 422 HH										
Protocol Number	MRN	Subject Name	Initial Consent Date	HH Order Name	Collected Date	Sodium - Na (mmol/L)	Potassium - K (mmol/L)	Chloride - Cl (mmol/L)	CO2 - Bicarbonate (mmol/L)	Urea Nitrogen - BUN (mg/dL)	Creatinine (mg/dL)
BTRIS- TEST- 03	4127614	NIHCCTEST, PATIENTBGJ MISS		PANEL	Jul 6, 2006 10:53:00 AM					5	6.0
BTRIS- TEST- 03	4127614	NIHCCTEST, PATIENTBGJ MISS		Creatinine Clearance	Jul 6, 2006 10:54:00 AM						4.0
BTRIS- TEST- 03	4127614	NIHCCTEST, PATIENTBGJ MISS		Chem 20 Panel	Jul 20, 2006 7:48:00 AM	136	4.2	102	24	15	1.2
BTRIS- TEST- 03	4122264	NIHCCTEST, PATIENTBN MIS		Chem 20 Panel	Feb 7, 2006 10:23:00 AM	140	3.5	100	23	10.	1.5
BTRIS- TEST- 03	4122264	NIHCCTEST, PATIENTBN MIS		Glucose,WB	Oct 13, 2006 8:19:00 AM						
BTRIS- TEST- 03	3981770	NIHCCTEST, PATIENTBO MIS		Acute Care	Jun 1, 2005 8:51:00 PM	120	5.0	131	20	5	8.0

- •Abnormal results are color-coded.
- •Results can be downloaded on to a spreadsheet.

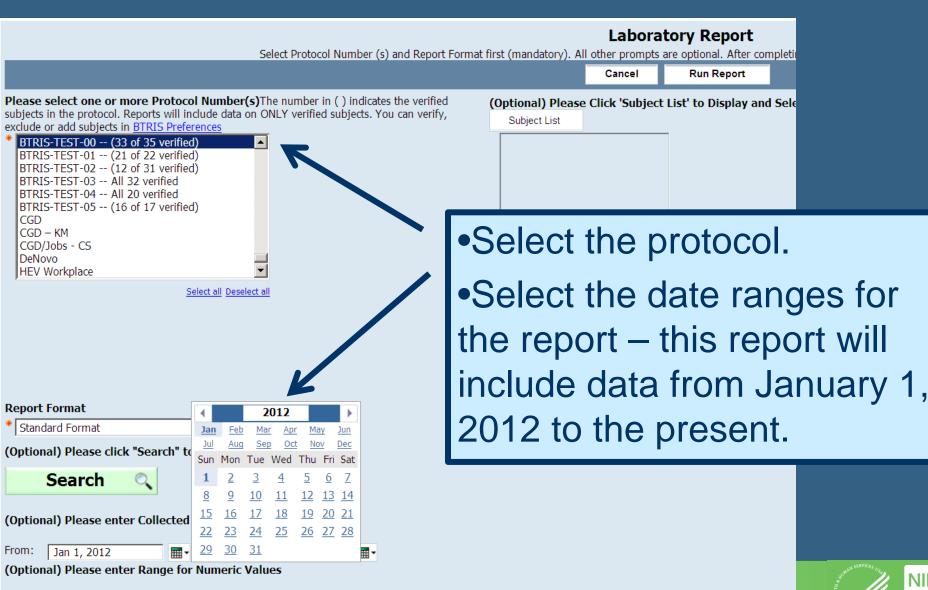
Run a Laboratory Report



•From the "Active Protocol" tab select the Laboratory Report.



Laboratory Report Prompt Page

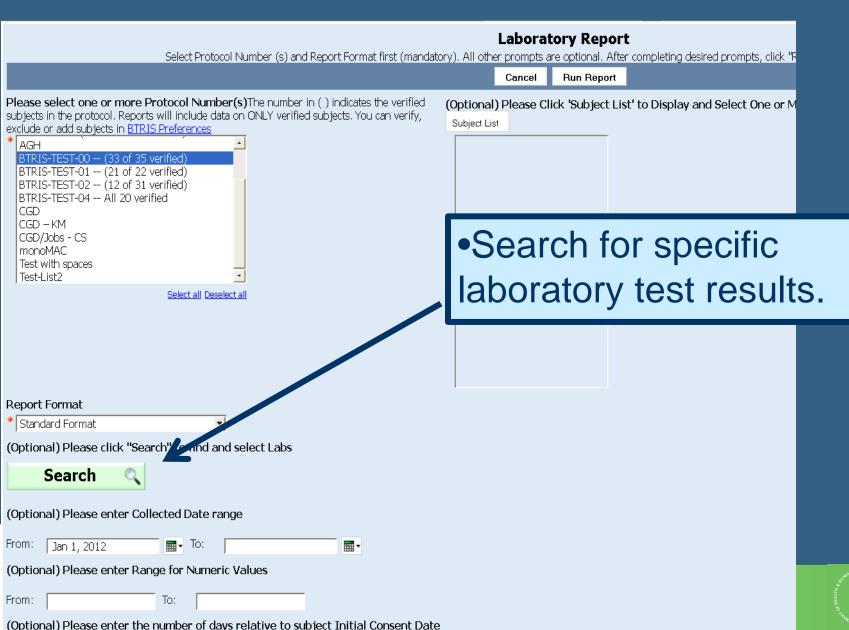


From:

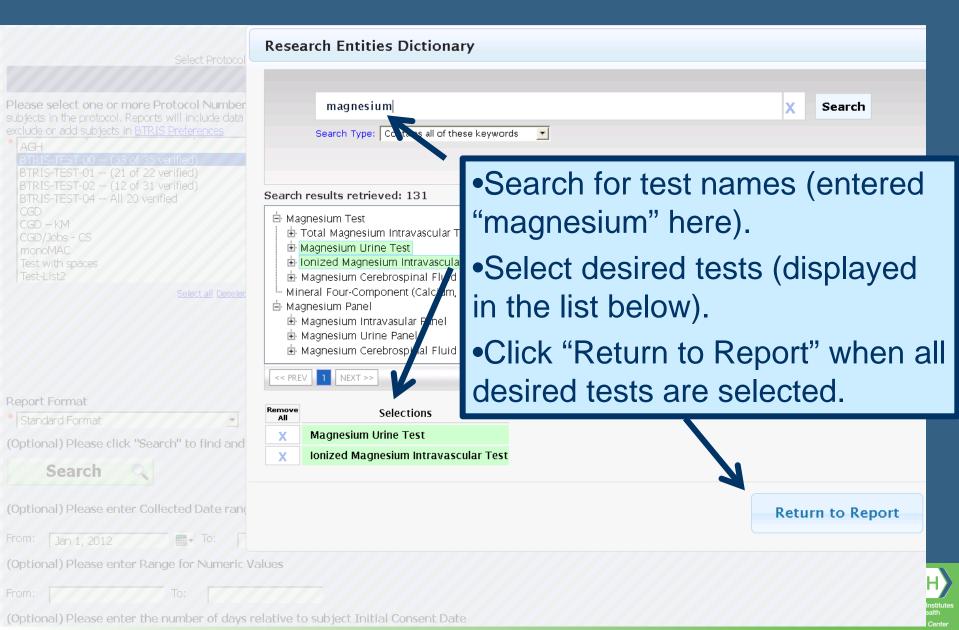
(Optional) Please enter the number of days relative to subject Initial Consent Date



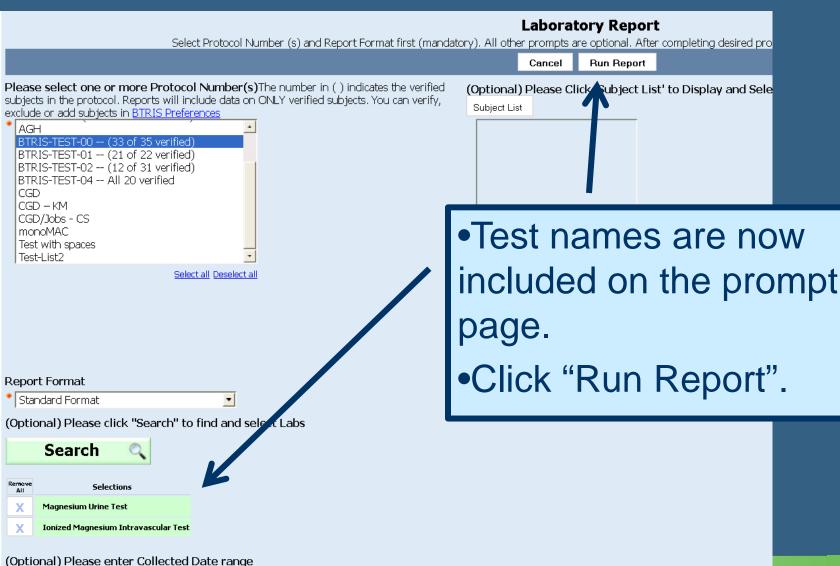
Laboratory Report Prompt Page



Searching the Dictionary



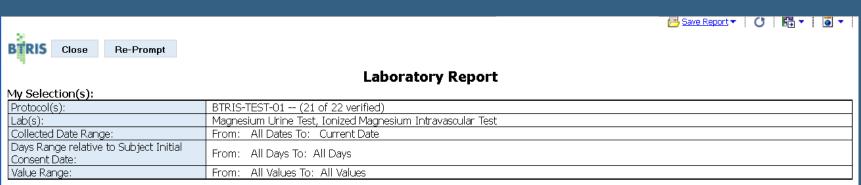
Laboratory Report Prompt Page





Jan 1, 2012

Laboratory Report



Report Format

* Standard Format

Subject Count: 2 Record Count: 14

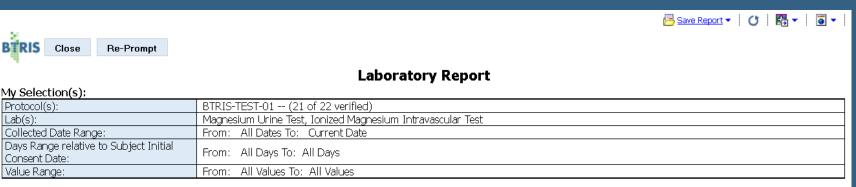
Protocol Number	MRN	Subject Name	Order Name	Collected Date Time	Observation Name
BTRIS- TEST-01	4122306	NIHCCTEST, PATIENTBI OPD	Chem 2, WB, Venous, OR	Oct 13, 2006 11:12:00 AM	Ionized Magnesium,WB, Ven
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Urine	Sep 7, 2008 11:07:00 AM	Magnesium, Urine
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Random Urine	Oct 14, 2008 3:21:00 PM	Magnesium, Random Urine
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Timed Urine	Oct 14, 2008 3:24:00 PM	Magnesium, Urine
BTRIS-	4224188	TEST, PATIENT	Magnesium, Timed	Oct 14, 2008 3:24:00 PM	Magnesium

- •This is the Lab Test Results Report.
- •Note that this report is in "standard format".

1E51-01		LAB INPATIENT	Random Urine		Random Urine	i Stariuaru iui		niliai .					
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Timed Urine	Oct 14, 2008 3:24:00 PM	Magnesium, Urine								
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Timed Urine	Oct 14, 2008 3:24:00 PM	Magnesium Excretion	9.32	Н		mmol/24h	3.00-4.25		CC-Labs	
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Chem 2, WB, Arterial, OR	Feb 4, 2010 10:25:00 AM	Ionized Magnesium,WB, Art	0.60			mmol/L	0.44-0.60		CC-Labs	
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Ionized Magnesium,WB, Ven	Sep 18, 2010 2:42:00 PM	Ionized Magnesium,WB, Ven	0.65			mmol/L			CC-Labs	
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Timed Urine	Sep 18, 2010 3:01:00 PM	Magnesium, Urine	1.80			mmol/L			CC-Labs	ı
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Magnesium, Timed Urine	Sep 18, 2010 3:01:00 PM	Magnesium Excretion	3.60			mmol/24h	3.00-4.25		CC-Labs	
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Chem 2, WB, Venous, OR	Sep 8, 2011 7:32:00 AM	Ionized Magnesium,WB, Ven	0.50			mmol/L	0.44-0.60		CC-Labs	, solic
BTRIS- TEST-01	4224188	TEST, PATIENT LAB INPATIENT	Chem 2, WB, Arterial, OR	Sep 8, 2011 7:32:00 AM	Ionized Magnesium,WB, Art	see below		Cannot be calculated.	mmol/L	0.44-0.60		CC-Labs	DE



Laboratory Report Format



1

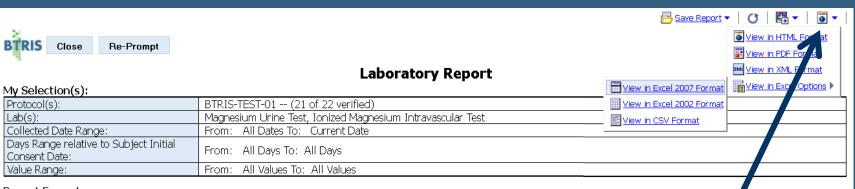
Report Format

* Crosstab Format (Numeric Values by Day)
The output displayed includes only true numeric values. Values such
>, -, 1-5 will not be i

Subject Name, MRN, Coll	ected Dat	te Time	Ionized Magnesium,WB, Ven	Magnesium, G.	Magnesiu
NIHCCTEST, PATIENTBI OPD	4122306	2006-10-13	0.77		
TEST, PATIENT LAB INPATIENT	4224188	2008-09-07		6	
TEST, PATIENT LAB INPATIENT	4224188	2008-10-14		5	
TEST, PATIENT LAB INPATIENT	4224188	2010-02-04			
TEST, PATIENT LAB INPATIENT	4224188	2010-09-18	0.65	1.8	
TEST, PATIENT LAB INPATIENT	4224188	2011-09-08	0.5		
TEST, PATIENT LAB INPATIENT	4224188	2011-11-04	0.6		

 You can select other formats, like "Crosstabs" to change the report from rows to columns.

Downloading Laboratory Results



Report Format

* Crosstab Format (Numeric Values by Day) 🗾

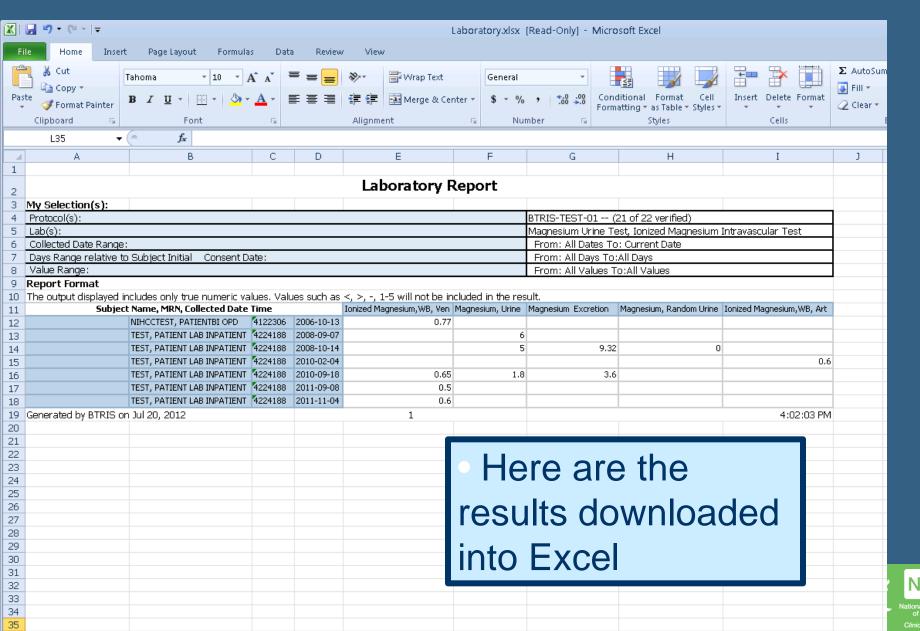
The output displayed includes only true numeric values. Values such as <, >, -, 1-5 will not be

Subject Name, MRN, Coll	ected Dat	te Time	Ionized Magnesium,WB, Ven	Magnesium, Urine	Magnesii
NIHCCTEST, PATIENTBI OPD	4122306	2006-10-13	0.77		
TEST, PATIENT LAB INPATIENT	4224188	2008-09-07		6	
TEST, PATIENT LAB INPATIENT	4224188	2008-10-14		5	
TEST, PATIENT LAB INPATIENT	4224188	2010-02-04			
TEST, PATIENT LAB INPATIENT	4224188	2010-09-18	0.65	1.8	
TEST, PATIENT LAB INPATIENT	4224188	2011-09-08	0.5		
TEST, PATIENT LAB INPATIENT	4224188	2011-11-04	0.6		

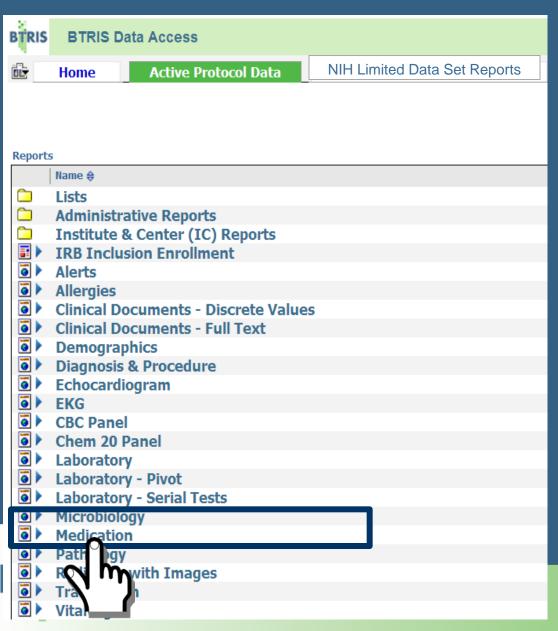
 Use the pull-down menu to select a format for downloading results to your computer

4:02:03 PM

Downloading Laboratory Results



Run a Medication Report



•From the "Active Protocol" tab select the Medication Report



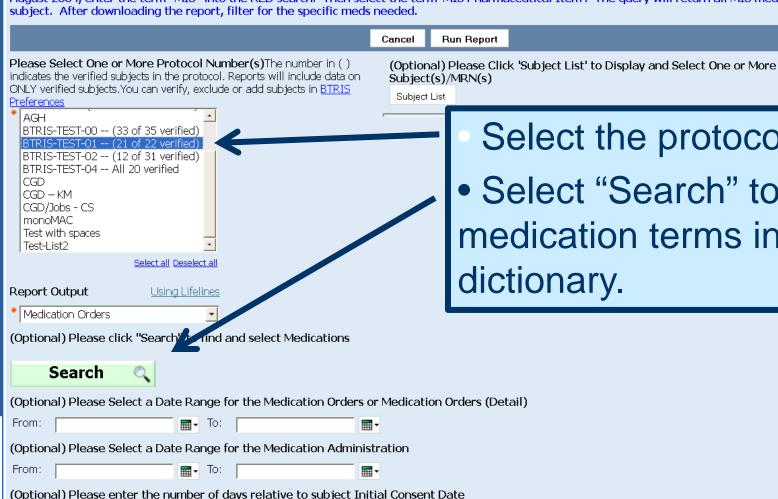
Medication Report Prompt Page

Medication Report

Select "Protocol Number (s)" first (mandatory). All other prompts are optional. After completing desired prompts, click "Run Report" to begin running report.

CURRENT MEDICATIONS - To search for medications from September 2004 to present, use specific medication names / classes to conduct a search.

HISTORIC MEDICATIONS - Historic medications from MIS are in BTRIS but not yet categorized or coded. To search for medications (ordered) prior to August 2004, enter the term "MIS" into the RED search. Then select the term "MIS Pharmaceutical Item". The guery will return all MIS medications for each



Select the protocol.

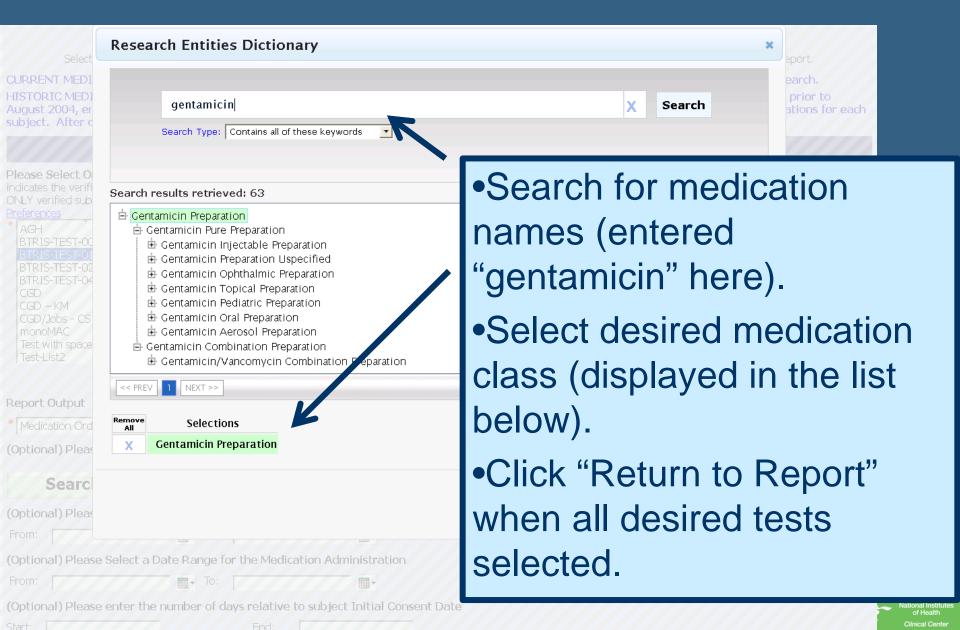
 Select "Search" to look for medication terms in the dictionary.



End:

Start:

Searching the Dictionary



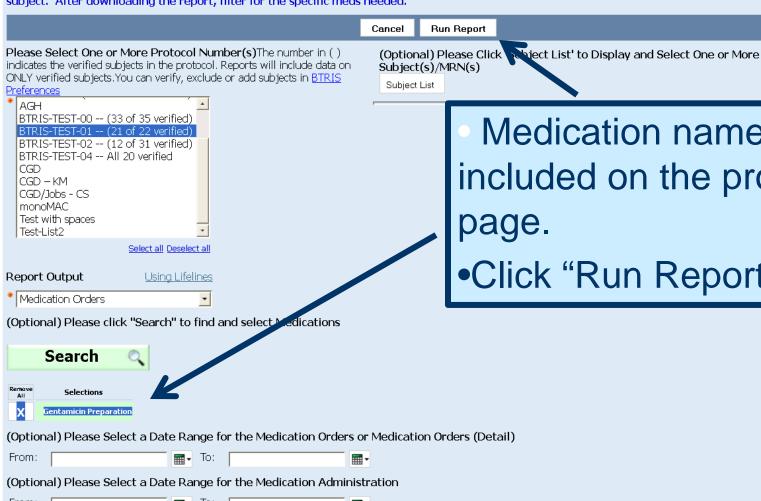
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Medication name now included on the prompt

•Click "Run Report".

From: **Ⅲ** - To:



Medication Report



Medication Report

My Selection(s):

Ty delection (a)						
Protocol(s) selected:	BTRIS-TEST-01 (21 of 22 verified)					
Medication Class(es) selected:	Gentamicin Preparation					
Order Date Range selected:	From: All Dates To: Current Date					
Administration Date Range selected:	From: All Dates To: Current Date					
Number of Days Range selected:	From: All Days To: All Days					

Report Output

* Medication Orders

Subject Count: 2 Record Count: 6

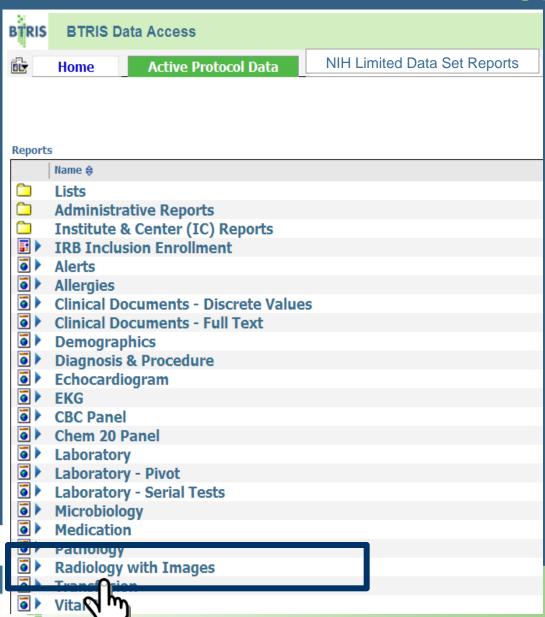
Medication results

Save Report ▼

Protocol Number	MRN	Subject Name	Medication Name	Order ID	Order Date / Start Date	Initial Consent Date	Data Source
BTRIS-TEST-01	3981770	NIHCCTEST, PATIENTBO MIS	Gentamicin Infusion	001NMN369			CC-CRIS
BTRIS-TEST-01	3981770	NIHCCTEST, PATIENTBO MIS	Gentamicin Infusion	001NGD977	Dec 1, 2005 3:00:00 PM		CC-CRIS
BTRIS-TEST-01	3981770	NIHCCTEST, PATIENTBO MIS	Gentamicin Infusion	001NMN250	Dec 23, 2005 10:00:00 AM		CC-CRIS
BTRIS-TEST-01	3981770	NIHCCTEST, PATIENTBO MIS	Gentamicin Infusion	001NMN255	Dec 24, 2005 11:00:00 AM		CC-CRIS
BTRIS-TEST-01	3981770	NIHCCTEST, PATIENTBO MIS	Gentamicin Infusion	001PNN153	Mar 21, 2006 4:42:43 PM		CC-CRIS
BTRIS-TEST-01	3623816	TEST, PATIENT GE DRD	Gentamicin Infusion	001GDQ040	Aug 27, 2004 2:21:00 PM		CC-CRIS



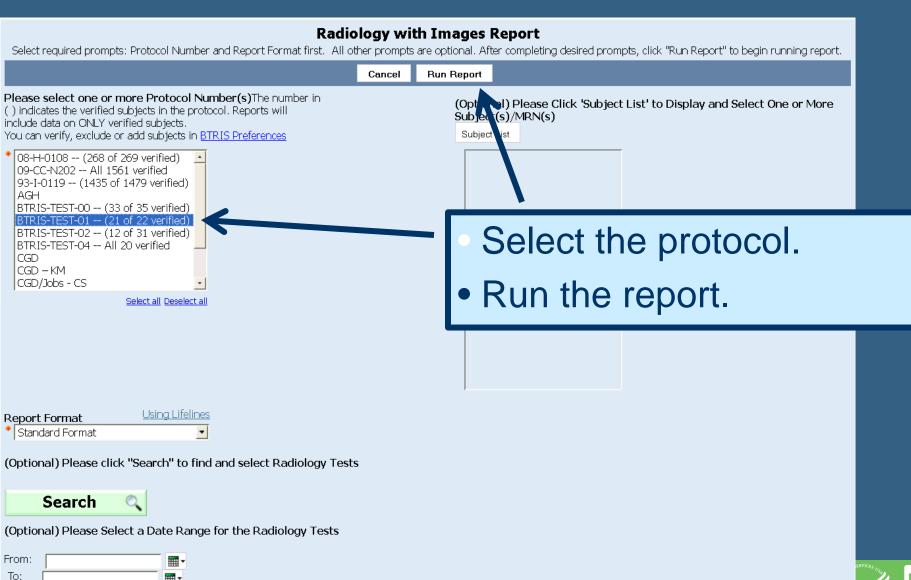
Run a Radiology Report



•From the "Active Protocol" tab select the Radiology with Images report

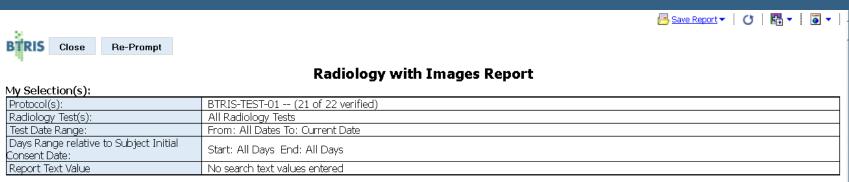


Radiology Report Prompt Page





Radiology Report



Report Format

* Standard Format

4026809 CONIHTEST,

A004000 CONTURED

PATIENTBL MIS

BTRIS-

DIDIO

TEST-01

Subject Count: 7 Record Count: 425

Protocol Number	MRN	Subject Name	Result Date	Test Name	
BTRIS- TEST-01	4026809	CCNIHTEST, PATIENTBL MIS	Nov 17, 2005 8:47:39 AM	CT Chest	Exam: CT Chest Report: 10-19-05 test from test tset test 10-19 _test test test test from new tset test from ORMI com

Sep 2, 2005

10:54:01 AM

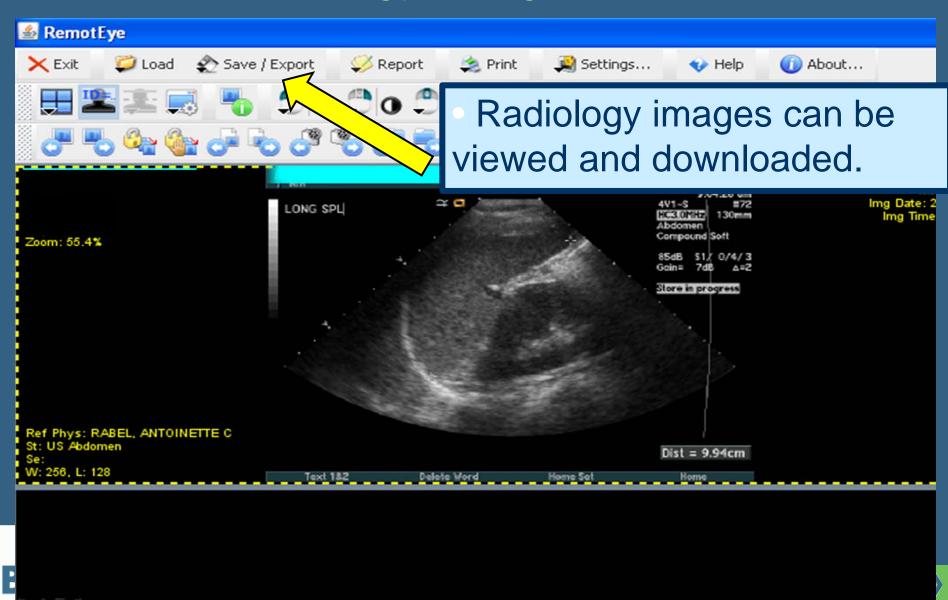
Companie

- Radiology results report.
- Click on hyperlinks to get images.

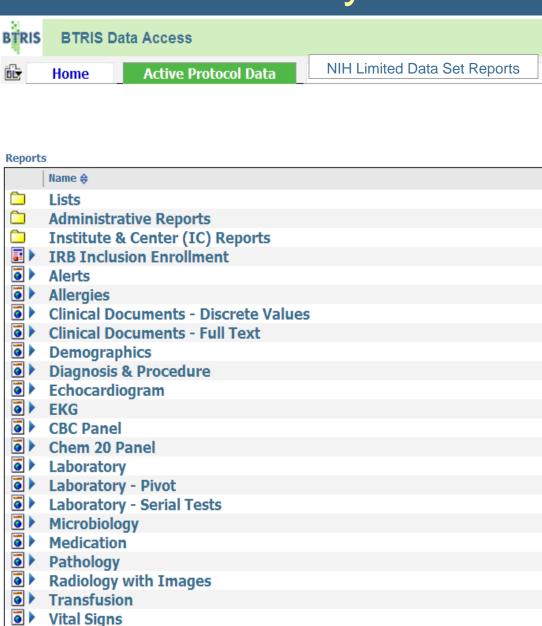
esrsdda 42.57747.4 nputer using 245.74 address update from 2c600 suite lan drop360 test test update test from nmdpet 97.98 - rebuilt PC This is a test from the new mcrm remote access computer - RW Dictated By: Radiologist, Test Signed By: Test Radiologist Signed Date: 11/17/2005 08:47 Transcribed By: Sanford, David C Transcribed Date: 09/09/2005 19:59 More Info: 2038993708 DX Chest - Single View DX0515532 CC-Radiology Exam: Exam Date: Accession #: DX Chest - Single View 9/2/05 DX-05-15532 lsjdfl;kjaslkfjowoiwlanaslkdjflkjaslfjsdal Dictated By: Choyke, Peter L. M.D. Signed By: Peter L. Choyke, M.D. Signed Date: 09/02/2005 10:54 Transcribed By: Sanford, David C Transcribed Date: 09/02/2005 10:53 More Info: 2038971268



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